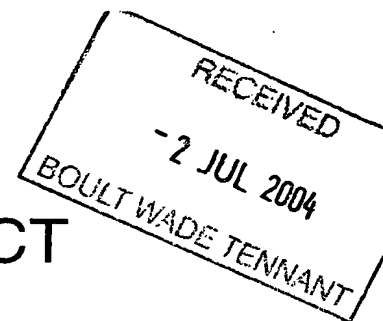


PATENT COOPERATION TREATY



From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

BAYLISS, GEOFFREY CYRIL
BOULT WADE TENNANT
VERULAM GARDENS
70 GRAY'S INN ROAD
LONDON WC1X 8BT
GRANDE BRETAGNE

HR Bayuss
9. 2/10/04

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

30.06.2004

Applicant's or agent's file reference
59862/001

IMPORTANT NOTIFICATION

International application No.
PCT/GB 03/01386

International filing date (day/month/year)
28.03.2003

Priority date (day/month/year)
28.03.2002

Applicant
BIOQUELL UK LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Fuerbass, C

Tel. +49 89 2399-8132



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 59862/001	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/01386	International filing date (<i>day/month/year</i>) 28.03.2003	Priority date (<i>day/month/year</i>) 28.03.2002
International Patent Classification (IPC) or both national classification and IPC A61L2/18		
Applicant BIOQUELL UK LIMITED et al.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 12 sheets.</p>

<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application
--

Date of submission of the demand 22.10.2003	Date of completion of this report 30.06.2004
Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>	Authorized Officer Maremonti, M Telephone No. +49 89 2399-8440



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/01386

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-4, 7-12, 14-20 as originally filed
5, 5a, 6, 13 received on 17.05.2004 with letter of 14.05.2004

Claims, Numbers

1-25 received on 17.05.2004 with letter of 14.05.2004

Drawings, Sheets

1/10-3/10, 6/10-10/10 as originally filed
4/10, 5/10 received on 17.05.2004 with letter of 14.05.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/01386**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-4,6-8,10,12,13,15,17-25
	No: Claims	1,5,9,11,14,16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-25
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents and particularly to the passages cited in the international search report, unless otherwise specified:

D1: US-A-4863688

D2: WO-A-0211774

D3: US-A-6096265

- 1.1 The present application does not meet the requirements of the PCT, because the subject-matter of independent claim 1 is not novel in the sense of Article 33(2) PCT. Document D1 discloses a method of *in situ* decontaminating an enclosure, i.e. an incubator, by means of a hydrogen peroxide vapour generated from a supply of hydrogen peroxide aqueous solution. According to D1, such a supply can be located within the enclosure to be decontaminated (cf. c. 3, l. 66-c. 4, l. 6). The hydrogen peroxide aqueous solution is vaporized and entrained into a flow of heated air. It is then distributed into the enclosure so that all surfaces are sterilized. After a time sufficient for the decontamination, the hydrogen peroxide vapour is removed from the enclosure.
Therefore, all features mentioned in claim 1 are known from D1.
- 1.2 Moreover, the present application does not meet the requirements of the PCT, because the subject-matter of independent claim 20 does not involve an inventive step in the sense of Article 33(3) PCT. Indeed, document D1 also discloses an apparatus for carrying out the decontamination method as described above, which apparatus can be in the form of a self-contained portable unit (cf. particularly c. 5, l. 2-6) and which comprises a duct provided with a fan for causing air to flow through the duct, a filter for filtering air, a heat source for heating air, means for holding a supply of hydrogen peroxide aqueous solution, means for delivering said aqueous solution to a heating/vaporization unit, wherein hydrogen peroxide vapour is produced and entrained into the flow of heated air and an outlet conduit to distribute the heated air-sterilant flow throughout the enclosure.
Hence, the subject-matter of claim 20 differs from the apparatus of D1 only in that a rotating nozzle is provided to deliver the air-sterilant flow throughout the enclosure.

The provision of a nozzle, particularly a rotating nozzle, at the end of the outlet conduit in the apparatus of D1 is regarded, however, as a standard design measure for a person skilled in the art. No particular technical effect appears to be associated to the presence of such a nozzle. In fact, it is common practice to put a nozzle at the end of an outlet duct in order to direct the delivered vapour onto the surface to be treated, see for example document D3. No inventive step can be acknowledged to such distinguishing feature (Article 33(3) PCT).

- 1.3 Dependent claims 2-19 and 21-25 do not appear to contain any additional feature which, in combination with the features of any claim to which they refer, meets the requirements of the PCT with respect to novelty and inventive step (Articles 33(2) and (3) PCT). All mentioned features are, indeed, either known from D1 or they are regarded as to represent obvious design possibilities for a person skilled in the art, also in view of D2 and D3. In particular, the possibility to operate in conditions that produce the hydrogen peroxide condensation on the surfaces to be decontaminated is well known in the sterilization art, as disclosed for example in D2, as well as the monitoring and controlling of the method operating conditions.
2. The subject-matter of all claims is regarded as to be industrially applicable (Article 33(4) PCT).
3. The following further observations on the present international application are noted:
 - 3.1 In claim 1, line 15-16, reference is made to "said supply". However, no supply was previously defined and it is not clear what should be intended (Article 6 PCT).
 - 3.2 Apparently, the term "aqueous solution of hydrogen peroxide/water vapour" in claim 1, line 15 should be read as "aqueous solution of hydrogen peroxide" (Article 6 PCT). The same applies to the corresponding passage of the description on p. 5a, l. 34-p. 6, l. 1.
 - 3.3 In claim 9, it is not clear what is intended by the term "source of air" and where the mentioned fans are in fact located with respect to such a source. Actually, such an embodiment does not appear to be supported by the description (Article 6 PCT).
 - 3.4 UK application number 0291983.1 as expressed on page 5, line 12 is not clear as this number is not accessible by the public. It should have been replaced by the

corresponding publication number.

- 3.5 It is clear from the description (see p. 9, l. 19-21 as a case in point), that the disclosed apparatus includes a heater in order to heat the air before adding the sterilant. However, such a heater is not mentioned in the independent apparatus claim 20. This feature is essential and as such it should have been included in claim 20 (Article 6 PCT). Moreover, in this way, also the necessary correspondence with the independent method claim 1, including the air heating step, would have been established (Article 6 PCT).
- 3.6 Independent claims 1 and 20 have been modified by using the two-part form. However, such adopted formulation is not appropriate in the present case since various features mentioned in the characterizing part of the claims are known from the cited state of the art (see items 1.1 and 1.2, above) (Rule 6.3 PCT).

10/509192

- 5 -

DT15 Rec'd PCT/P10 24 SEP 2001

The apparatus and method described in the present invention will work equally well with both the dry and condensation processes. When operating a dry process it is
5 essential to monitor the water and hydrogen peroxide concentration in the gaseous phase to ensure that they remain below the saturated vapour concentrations. When operating a condensation process it is helpful to have an indication of the point during the cycle when condensation
10 starts to form and the subsequent rate of formation. A technique and apparatus to make such a measurement of condensation is described patent application UK 0291983.1

An ideal bio-decontamination cycle is in three phases.
15 The first phase is to bring all of the equipment to thermal stability but may also be used to adjust the relative humidity in the chamber to a pre-set level, the second is used to raise the gas concentration to the required level and maintain that concentration for a sufficient length of
20 time to achieve the required level of bio-decontamination, and the third and last phase to reduce the concentration of the sterilant in the enclosed space to a predetermined value.

25 US-A-4863688 discloses a method of selectively destroying organisms within a chamber such as an incubator comprising the steps of introducing vapour phase hydrogen peroxide into the chamber at a rate sufficient to cause a predetermined concentration of hydrogen peroxide to be
30 reached while preventing a substantial change in pressure or condensation of the hydrogen peroxide in the chamber. When the predetermined period of time has elapsed, the vapour phase hydrogen peroxide is removed from the chamber. In a preferred embodiment disclosed an incubator is provided with

- 5a -

a separate apparatus for producing a flow of air containing hydrogen peroxide vapour which is delivered to the incubator. Alternatively the apparatus for producing the
5 air flow containing hydrogen peroxide vapour may be built into the incubator.

RU-C-2054295 discloses a device for sanitary treatment of air for use in livestock and poultry facilities and in
10 various branches of industry including biological, food, light industry, chemical, coal, construction and other applications. The device includes a housing with an inlet and an outlet, a heating element, disinfected evaporator in the form of a perforated header closed at one end and
15 enclosed in a porous sheath, the header is installed along the housing axis. The device has a reservoir containing disinfectant solution secured to the housing and connected to the open end of the evaporator. The tubular evaporator is arranged in the porous sheath along a spiral line and the
20 heating element is mounted within the centre of the spiral.

This invention provides a method of decontaminating an enclosed space comprising the steps of providing an aqueous solution of hydrogen peroxide in the enclosed space,
25 producing hydrogen peroxide/water vapour from said aqueous solution, creating an air stream in the enclosed space, introducing hydrogen peroxide/water vapour into the air stream, distributing the hydrogen peroxide/water vapour containing air stream throughout the space to be
30 decontaminated and then removing the hydrogen peroxide/water vapour from the space; characterised in that the air stream is heated before hydrogen peroxide/water vapour is introduced to it, the hydrogen peroxide/water vapour is flash evaporated from an aqueous solution of hydrogen

- 6 -

peroxide/water vapour from said supply into the air stream, and the air stream carrying the flash evaporated hydrogen peroxide/water vapour is distributed throughout the enclosed space to achieve bio-decontamination of the enclosed space.

By placing the gas generator inside the room and simply heating the carrier gas and then evaporating this sterilant into the air stream it is possible to use the available energy much more efficiently. The increase in efficiency is derived from the removal of the system for decomposing and drying the carrier gas, and also because there is no need for any pipe work to transport the carrier gas and decontaminant from an external generator.

15

This increased efficiency provides more energy for the primary function of heating the carrier gas and flash evaporating the liquid. The efficiency increase is so great as it allows a trebling of the rate of flash evaporation from the same energy source and hence the rate of increase in the gas concentration or the achievable rate of formation of condensation once the dew point has been reached is also trebled.

The simplified design is also much smaller and lighter than a conventional gas generator and hence considerably less expensive to manufacture. It is therefore realistic to place a number of such devices inside a sealed enclosure to be decontaminated. This reduction in size and weight makes the apparatus portable and hence makes it practical to use the same apparatus to bio-decontaminate a number of facilities either on the one site or at different locations. As stated above it is important to make measurements of

35

547757; GCB; LMB

- 13 -

thereof in which the outlet conduit 40 extends stopping short of the bottom of the cavity. The block 30 has a multiplicity of axially extending passageways 38 adjacent the outer surface of the block and spaced around the block leading from the lower recess 31 and the block upper recess 34 for flow of air from the bottom recess to the top recess from where the air can flow into the cavity 37 and thence into the outlet conduit 40. The liquid sterilant from the storage container 15 is delivered via one or more inlet conduits 41 providing injection points which extend through the top plate 35 adjacent to the outlet conduit 40. The conduits 41 lead into the cavity 37 in the block but stop short of the bottom of the cavity. A second inlet conduit 41 is shown and preferably three such conduits are provided at spaced locations around the outlet conduit.

The body 30 is encircled by a cylindrical jacket in which an electrical resistance heater 42 is mounted for heating the body 30 to a requisite temperature to pre-heat the airflow through the block and also to ensure that sterilant delivered by the conduit 14 to the bottom of the cavity 37 of the block is flash evaporated from the bottom of the cavity to produce a vapour which is entrained in the flow of air through the flow of heated air through the outlet conduit 40 for delivery into the room to be sterilised.

The heating unit of the heater-evaporator is coupled to the control unit to the apparatus and a temperature probe 44 is mounted in a radial drilling 45 in the body 30 below the cavity 37 to measure the temperature of the body for adjusting, through the

CLAIMS:

1. A method of decontaminating an enclosed space comprising the steps of providing an aqueous solution of hydrogen peroxide in the enclosed space, producing hydrogen peroxide/water vapour from said aqueous solution, creating an air stream in the enclosed space, introducing hydrogen peroxide/water vapour into the air stream, distributing the hydrogen peroxide/water vapour containing air stream throughout the space to be decontaminated and then removing the hydrogen peroxide/water vapour from the space; characterised in that the air stream is heated before hydrogen peroxide/water vapour is introduced to it, the hydrogen peroxide/water vapour is flash evaporated from an aqueous solution of hydrogen peroxide/water vapour from said supply into the air stream, and the air stream carrying the flash evaporated hydrogen peroxide/water vapour is distributed throughout the enclosed space to achieve bio-decontamination of the enclosed space.
2. A method as claimed in claim 1, characterised in that hydrogen peroxide/water vapour is added to the flow of heated air distributed in the enclosure until the dew point of the vapour is reached and condensation of hydrogen peroxide/water vapour on the surfaces of the enclosure takes place following which the hydrogen peroxide is removed from the enclosed space.
3. A method as claimed in claim 2, characterised in that the condensation of the hydrogen peroxide/water vapour is measured by a monitor and when the condensation has reached

- 22 -

a requisite level, air flow containing hydrogen peroxide/water vapour is terminated.

4. A method as claimed in claim 2 or claim 3,
5 characterised in that condensation is measured in the enclosure at a number of locations by condensation monitors to ensure that condensation has taken place throughout the enclosure.

10 5. A method as claimed in claim 1, characterised in that air carrying hydrogen peroxide/water vapour is introduced into the enclosure until a predetermined concentration of hydrogen peroxide/water vapour in the atmosphere in the enclosure has been reached after which introduction of the
15 air is terminated and the hydrogen peroxide is removed.

6. A method as claimed in claim 5, characterised in that
biological indicators are used in the enclosure to determine
when the concentration of hydrogen peroxide/water vapour in
20 the atmosphere in the enclosure has reached the requisite level following which the hydrogen peroxide is removed.

7. A method as claimed in any of the preceding claims,
characterised in that the heated air carrying hydrogen
25 peroxide/water vapour is delivered as a jet within the enclosure.

8. A method as claimed in claim 7, characterised in that
the heated air carrying hydrogen peroxide/water vapour is
30 delivered in a universally rotating jet to distribute the vapour throughout the enclosure.

9. A method as claimed in any of the preceding claims, characterised in that one or more fans are provided spaced from the source of air carrying hydrogen peroxide/ water vapour into the enclosure to deliver the air carrying the vapour to remote locations of the enclosure from said source.

10. A method as claimed in any of the preceding claims, characterised in that the vapour of hydrogen peroxide and water also contains peracetic acid.

11. A method as claimed in claim any of claims 1 to 9, characterised in that the solution from which the hydrogen peroxide/water vapour is produced contains 30 to 35% hydrogen peroxide and a balance of water.

12. A method as claimed in claim 10, characterised in that the solution from which the hydrogen peroxide solution is produced comprises 15% hydrogen peroxide, 0.5% peracetic acid and a balance of water.

13. A method as claimed in any of the preceding claims, characterised in that hydrogen peroxide is removed by circulating the air containing hydrogen peroxide over a catalyst.

14. A method as claimed in any of claims 1 to 8, characterised in that the enclosure has a heating/ventilation air conditioning system, the hydrogen peroxide is removed from the enclosure using the heating/ventilation air conditioning system.

15. A method as claimed in any of the preceding claims, characterised in that a plurality of heated air flows are provided to which the hydrogen peroxide/water vapour is added to provide a plurality of flows of heated air carrying
5 hydrogen peroxide/water vapour at different locations in the enclosure.

16. A method as claimed in any of the preceding claims, characterised in that the method is controlled from outside
10 the enclosure.

17. A method as claimed in any of the preceding claims, characterised in that the air is dehumidified to reduce the relative humidity in the enclosure to a predetermined level
15 prior to delivering heated air containing hydrogen peroxide/water vapour to the enclosure.

18. A method as claimed in claim 17, characterised in that the air is dehumidified using an air conditioned system for
20 the enclosed space.

19. A method as claimed in any of the preceding claims, characterised in that a portable apparatus is used in the enclosure having a duct with a fan for delivering air
25 through the duct, a filter for filtering air entering the duct, a heater for heating air passing through the duct and means for delivering hydrogen peroxide/water vapour to the air passing through the duct and a nozzle for delivery of
30 air carrying hydrogen peroxide/ water vapour from the duct, the nozzle being rotated universally to distribute the hydrogen peroxide/water vapours throughout the enclosure,

- 25 -

circulation of air carrying the hydrogen peroxide/water vapour through the duct causing decontamination of the duct.

20. An apparatus for decontaminating an enclosed space
5 comprising means (12,13) for providing a flow of heated air,
and means (15,16) for delivering a liquid decontaminant to
the heated air to be evaporated into the heated air to
produce an air stream containing a vapour of the
decontaminant for delivery to a space to be decontaminated;
10 characterised in that the apparatus comprises a
self-contained unit having a duct (10) to be positioned
within the enclosed space having an inlet end and an outlet
end, a fan (12) for causing air to flow from the enclosed
space through the duct, a filter (11) for filtering air at
15 the inlet end of the duct, means (15) for holding a supply
of aqueous hydrogen peroxide solution, means (16) for
delivering aqueous hydrogen peroxide solution from said
holding means to a heater (14) to flash evaporate the
aqueous hydrogen peroxide to produce hydrogen peroxide/water
20 vapour which is entrained in the air flow passing through
the duct, a nozzle (18) at the outlet end of the duct and
means (17) to rotate the nozzle universally to deliver
hydrogen peroxide/water vapour throughout the enclosure, all
internal and external surfaces of the apparatus open to the
25 enclosure being exposed to the hydrogen peroxide/water
vapour carrying air in the enclosure to decontaminate the
surfaces.

21. An apparatus as claimed in claim 20, characterised in
30 that the components of the apparatus are mounted in a
support (19) for transport of the apparatus.

22. An apparatus as claimed in claim 21, characterised in that the self-contained unit is a mobile or portable unit for movement from location to location where it is to be used.

5

23. An apparatus as claimed in claim 22, characterised in that the supply (15) of hydrogen peroxide/water vapour and/or the nozzle and means (18a) to rotate the nozzle are readily removable for transport of the apparatus.

10

24. An apparatus as claimed in any of claims 20 to 23 including a control box (70) for controlling operation of the apparatus, wherein means are provided for delivering air carrying hydrogen peroxide/water vapour from the atmosphere in the enclosure through the control box to decontaminate inner surfaces of the control box.

15

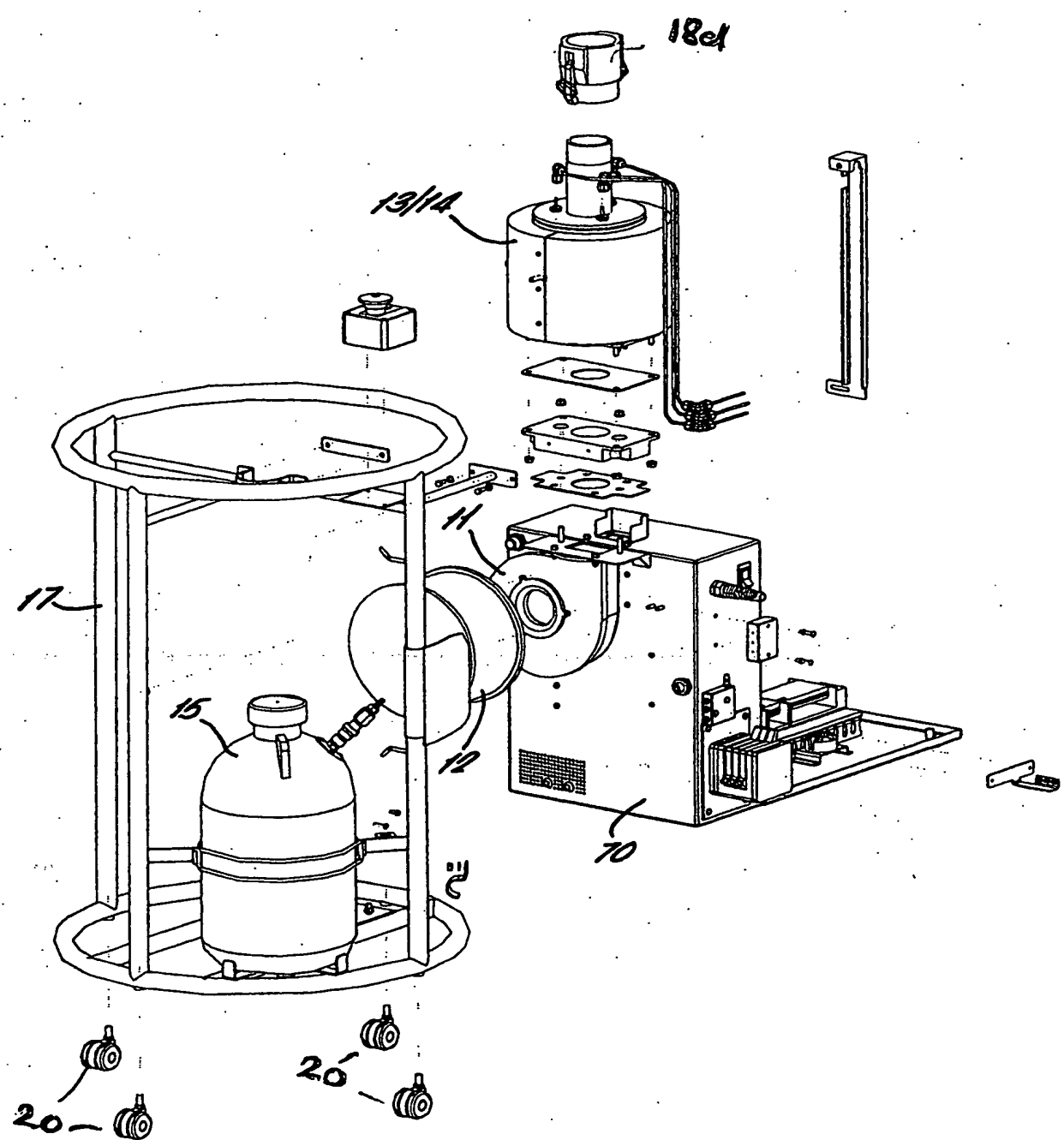
25. An apparatus as claimed in any of claims 20 to 24 including a separate monitoring unit for monitoring the temperature of the atmosphere in the enclosure and the concentration of hydrogen peroxide/ water vapour in the atmosphere, wherein means are provided for delivering a flow of air carrying hydrogen peroxide/water vapour through the enclosure of the monitoring unit to decontaminate interior surfaces of the monitoring unit.

20

25

4/10

FIG. 4.



5/10

FIG. 5.

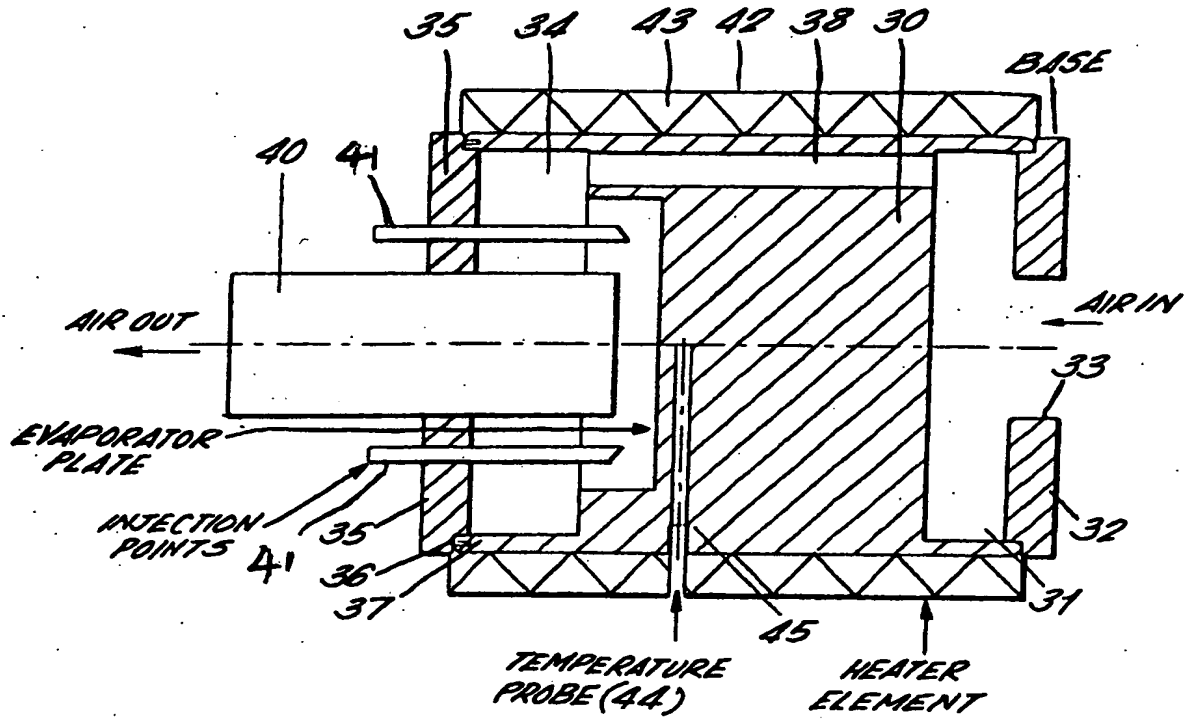


FIG. 6.

